

The following IQ / OQ is intended to be a guideline, local IQ / OQ procedures can vary depending on application and items stored in the Gram BioLine cabinet.

Deviations from the specifications dictated in the PQ are to be reported in the deviation report.

The IQ / OQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

This IQ / OQ is intended for the following product series:

BioCompact / BioCompact II

Customer:

Location of installation:

Model:

Serial number:

Item number - manual:

Status of operation:

- Active
- Inactive

Name of distributor:

Warranty:

Start: _____

End: _____

Instructions on use to starting the cabinet:

1. Training of the responsible party Date: _____ By: _____

2. Operational test of the cabinet Date: _____ By: _____

3. Responsible party _____ Tel: _____

Instructions to users:

The responsible party is trained in use of the cabinet in reference to the user manual

General use of cabinet

Objections to the mentioned:

Service & maintenance

The cabinet was delivered without defects/damage.
The cabinet started as specified in the user manual

Set values:

Setpoint temperature _____ °C

Local alarm settings

High temperature alarm _____ °C

Low temperature alarm _____ °C

External alarm settings

(See voltage free contact in user manual)

High temperature alarm _____ °C

Low temperature alarm _____ °C

Factory settings:

Model / Setpoint temp.		LHL	LLL	EHL	ELL
RF / BF	-20 °C	+25 °C	-35 °C	+25 °C	-35 °C
EF/PF 425	-40 °C	+25 °C	-60 °C	+25 °C	-60 °C
EF/PF 6XX	-35 °C	+25 °C	-45 °C	+25 °C	-45 °C
ER	+5 °C	+25 °C	-5 °C	+25 °C	-5 °C
RR	+5 °C	+25 °C	0 °C	+25 °C	0 °C
BR	+4 °C	+6 °C	+2 °C	+25 °C	0 °C

Date: _____ Name of trained user: _____ Signature: _____ Name of instructor: _____ Signature: _____

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
I-1	Ensure the cabinet is installed indoors.	Page 4				
I-2	Ensure the cabinet is installed in a sufficiently dry/ventilated area.	Page 4				
I-3	Ensure the cabinet is not in direct contact with sunlight or other heat sources.	Page 4				
I-4	Ensure that the ambient operating temperature is within the allowed range.	Page 4				
I-5	Ensure that the cabinet is not installed in a corrosive environment.	Page 4				
I-6	Ensure that the protective film on the cabinet is removed.	Page 4				
I-7	Ensure that the cabinet is cleaned.	Page 4				
I-8	Ensure that the cabinet has stood upright for 24 hours if it has lain down.	Page 4				
I-9	Ensure that the cabinet is levelled if it is equipped with legs.	Page 4				
I-10	Ensure a level surface if the cabinet is equipped with wheels/casters.	Page 4				
I-11	- If equipped with wheels/casters - Ensure wheels/casters are locked after positioning	Page 4				
I-12	- If equipped with drawers / glass door - Ensure that tilt-bracket is mounted.	Page 5				
I-13	Ensure that the cabinet is maximum 75mm from the back wall.	Page 6				
I-14	Ensure that there is minimum a gap of 30mm between cabinets.	Page 6				
I-15	Ensure that the top of the cabinet is not covered.	Page 6				
I-16	Ensure that electrical appliances are not being operated in the cabinet.	Page 6				

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
I-17	Ensure connection from voltage-free contact to external monitoring system (optional).	Page 7				
I-18	Ensure the correct set-point for the low temperature protection (if applicable).	Page 8				
I-19	Ensure the correct electrical connection (compare local values with type/nr plate).	Page 9				
I-20	Ensure that the power cord is secured in the terminal box with hanger.	Page 9				
I-21	Mark power cord with: "Do not separate when energized".	Page 9				

Model: _____ SN: _____

Please note: Page references to the manual are dependent on the model in question.

Operation Qualification - OQ

ID	Description of operation	Reference in manual BCII	Reference in manual BC	Comply		Attachmet	Notes
				YES	NO		
O-1	Turn on the cabinet - Display test (software version and variant).	Page 10	Page 26				
O-2	Set/adjust set-point temperature.	Page 10	Page 26				
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 13	-				
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 13	-				
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 14	-				
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 14	-				
O-7	Activate / deactivate dA - door alarm (local).	Page 15	Page 29				
O-8	Set/adjust dAd - delay for door alarm (local).	Page 15	Page 29				
O-9	Activate / deactivate bU - acoustic alarms (local).	Page 16	Page 30				
O-10	Set/adjust EHL - Upper alarm limit (external).	Page 17	-				
O-11	Set/adjust ELL - Lower alarm limit (external).	Page 17	-				
O-12	Set/adjust EHd - delay for upper alarm limit (external).	Page 18	-				
O-13	Set/adjust ELd - delay for lower alarm limit (external).	Page 18	-				
O-14	Activate / deactivate dA - door alarm (external).	Page 19	Page 31				
O-15	Set/adjust dAd - delay for door alarm (external).	Page 19	Page 31				
O-16	Activate / deactivate bU - acoustic alarms (external).	Page 20	Page 32				
O-17	Set/adjust defrost cycles per 24 hours (factory setting: 4).	Page 22	Page 34				
O-18	Select reference sensor for the display (A or E).	Page 23	-				

Model: _____ SN: _____

Deviation Report

Deviations to the criteria of acceptance are to be documented in the deviation report. A separate deviation report shall be made for each deviation. Mark the entry with the relevant “-ID” specified in the left column in the test specifications.

-ID: _____

Description of deviation:

Extent to which the deviation has been alleviated:

Additional notes:

Person responsible for test:

Name: _____

Date: _____

Company: _____

Signature: _____

Person responsible for verification of test:

Name: _____

Date: _____

Company: _____

Signature: _____

Model: _____ SN: _____

Approval of test results - Installation Qualification (IQ)

- The steps in the Installation Qualification - IQ were completed with positive results
- The steps in the Installation Qualification - IQ were completed with negative results

ID of steps with negative results: _____

Approval of test results - Operation Qualification (OQ)

- The steps in the Operation Qualification - OQ were completed with positive results
- The steps in the Operation Qualification - OQ were completed with negative results

ID of steps with negative results: _____

Customer / Responsible party _____

Trainer / Responsible party _____

Stamp & Signature _____

Stamp & Signature _____

Tel. _____

Tel. _____

E-mail _____

E-mail _____

Location & Date _____

Location & Date _____

Model: _____ SN: _____

Customer:	Location of installation:
_____	_____
_____	_____
_____	_____

Model: _____ SN: _____ Item number: _____
(manual)

The PQ consists of inspections of the correct operation of the cabinet under predefined conditions and procedures. Prerequisites for the PQ are IQ (Installation Qualification) and OQ (Operation Qualification), these must be concluded successfully prior to the initiation of the PQ.

This PQ is intended for the following product series:

BioCompact, BioCompact II, BioPlus, BioMidi

Person responsible for the cabinet:
Name: _____
Date: _____
Signature: _____
Person responsible for test:
Name: _____
Date: _____
Company: _____
Signature: _____
Person responsible for verification of test:
Name: _____
Date: _____
Company: _____
Signature: _____
Test duration:
Initiation (date/time): _____
Conclusion (date/time): _____

Model: _____ SN: _____

Name list - *Persons involved in the test procedure and subsequent report*

Date	Name	Company	Signature

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Prerequisites

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-1	The cabinet must be empty while conducting tests, ie without interior fittings such as drawers, shelves etc. Attachment: Notes:		
P-2	The measurements must be conducted in accordance to IEC 60068-3-5, measured in air with thermocouples or comparable equivalent. Attachment: Notes:		
P-3	The positioning of the sensors in the cabinet must be documented with a sketch and/or a photograph. Attachment: Notes:		

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model:

SN:

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Prerequisites

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-4	Measurements made during the PQ tests must be documented and attached to the PQ. Attachment: Notes:		
P-5	Specify setpoint temperature: _____ °C Specify the ambient temperature: _____ °C Attachment: Notes:		
P-6	Temperature fluctuations - <i>Select the correct temperature fluctuation range according to the model being tested.</i> <i>Find model-specific temperature fluctuations in appendix.</i> Tolerance: +/- _____ K Attachment: Notes:		

Name: _____ Signature: _____ Approved (Yes / No): _____ Date: _____

Conducted by: _____

Inspected / verified by: _____

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Temperature stabilization

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-7	<p>The test is intended to provide substantiation for the temperature stability inside the cabinet during normal operation.</p> <p>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature.</p> <p>When the system is stable, document ordinary operation of the cabinet at the setpoint temperature and ambient temperature specified in P-5.</p> <p>Duration: _____</p> <p>The measurements throughout the operation test, must be documented and attached the PQ.</p> <p>Attachment:</p> <p>Notes:</p>		
P-8	<p>Are the measurements inside the allowed temperature fluctuations specified in P-6 ?</p> <p>Attachment:</p> <p>Notes:</p>		

Name: _____ Signature: _____ Approved (Yes / No): _____ Date: _____

Conducted by: _____

Inspected / verified by: _____

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Door opening test

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-9	<p>The test is intended to provide substantiation for the temperature recovery time inside the cabinet subsequently after a door opening.</p> <p>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature, the setpoint temperature is specified in P-5.</p> <p>When the system is stable, open the door at 90° for 60 seconds.</p> <p>The measurements, throughout the door opening test, must be documented and attached the PQ.</p> <p>Duration: _____</p> <p>Attachment:</p> <p>Notes:</p>		
P-10	<p>Have the setpoint temperature specified in P-5, measured in the absolute centre of the cabinet, been achieved within the set time-frame?</p> <p>Attachment:</p> <p>Notes:</p>		

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model:

SN:

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Pull-down

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-11	<p>The test is intended to provide substantiation for the time it takes for the inside of the cabinet to reach the setpoint temperature specified in P-5. The initial temperature in the working space is the ambient temperature specified in P-5. The temperature inside the cabinet must be stabilized in all points of the working space.</p> <p>When the system is stable. Turn on the power to the cabinet.</p> <p>The measurements, throughout the pull-down test, must be documented and attached the PQ.</p> <p>Attachment:</p> <p>Notes:</p>		
P-12	<p>The time it takes the inside of the cabinet to achieve the setpoint temperature measured in the absolute centre, must not exceed the time-frame specified in the appendix.</p> <p>Duration: _____</p> <p>Have the criteria been met?</p> <p>Attachment:</p> <p>Notes:</p>		

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model:

SN:

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
 The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Hold-over

ID	DESCRIPTION	ACCEPTED	
		YES	NO
P-13	<p>The test is intended to provide substantiation for the time it takes for the temperature inside the cabinet to reach the terminal temperature specified in the appendix. Ambient temperature and setpoint temperature is specified in P-5.</p> <p>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature throughout, the temperature fluctuations are specified in P-6.</p> <p>When the system is stable, turn off the power to the cabinet.</p> <p>The measurements, throughout the hold-over test, must be documented and attached the PQ.</p> <p>Attachment:</p> <p>Notes:</p>		
P-14	<p>The times it takes the inside of the cabinet to reach the terminal temperature, must at least be the time specified in the appendix.</p> <p>Duration: _____</p> <p>Have the criteria been met?</p> <p>Attachment:</p> <p>Notes:</p>		

Name: _____ Signature: _____ Approved (Yes / No): _____ Date: _____

Conducted by: _____

Inspected / verified by: _____

Model: _____ SN: _____

Deviation Report

Deviations to the criteria of acceptance are to be documented in the deviation report. A separate deviation report shall be made for each deviation. Mark the entry with the relevant "P-ID" specified in the left column in the test specifications.

P-ID: _____

Description of deviation:

Extent to which the deviation has been alleviated:

Additional notes:

Person responsible for test:

Name: _____

Date: _____

Company: _____

Signature: _____

Person responsible for verification of test:

Name: _____

Date: _____

Company: _____

Signature: _____

Model: _____

SN: _____

Approval of test results - Performance Qualification (PQ)

- The steps in the Performance Qualification - PQ were completed with positive results
- The steps in the Performance Qualification - PQ were completed with negative results

ID of steps with negative results: _____

Additional notes:

Person responsible for test

Person responsible for verification of test

Stamp & Signature

Stamp & Signature

Tel.

Tel.

E-mail

E-mail

Location & Date

Location & Date

Model: _____ SN: _____

Appendix:

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over		
RR	BioCompact/BioCompact II	+/- 3K	210 (Solid door)	5 Minutes	25 Minutes	5°C → 10°C	55 Minutes	
	210 (Glass door)		6 Minutes	35 Minutes	30 Minutes			
	310 (Solid door)		5 Minutes	25 Minutes	55 Minutes			
	310 (Glass door)		6 Minutes	30 Minutes	32 Minutes			
	410 (Solid door)		6 Minutes	28 Minutes	62 Minutes			
	410 (Glass door)		7 Minutes	35 Minutes	35 Minutes			
	610 (Solid door)		3 Minutes	20 Minutes	66 Minutes			
	610 (Glass door)		3 Minutes	25 Minutes	40 Minutes			
	BioMidi	+/- 3K	425 (Solid door)	3 Minutes	20 Minutes	5°C → 10°C	63 Minutes	
	425 (Glass door)		4 Minutes	25 Minutes	37 Minutes			
	625 (Solid door)		3 Minutes	20 Minutes	63 Minutes			
	625 (Glass door)		4 Minutes	25 Minutes	37 Minutes			
	ER	BioPlus	+/- 2K	500 (Solid door)	3 Minutes	22 Minutes	5°C → 10°C	72 Minutes
		500 (Glass door)		4 Minutes	28 Minutes	42 Minutes		
600D / 600W (Solid door)		3 Minutes		20 Minutes	70 Minutes			
600D / 600W (Glass door)		4 Minutes		25 Minutes	41 Minutes			
660D / 660W (Solid door)		3 Minutes		20 Minutes	70 Minutes			
660D / 660W (Glass door)		4 Minutes		25 Minutes	41 Minutes			
930 (Solid door)		5 Minutes		22 Minutes	65 Minutes			
1270 / 1400 (Solid door)		5 Minutes		23 Minutes	78 Minutes			
1270 / 1400 (Glass door)		7 Minutes		29 Minutes	45 Minutes			

* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14

Note:

RR/ER :

Ambient temperature +25°C

Setpoint temperature +5°C

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model:

SN:



Appendix:

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over	
RF	BioCompact/BioCompact II						
	210	**	**	60 Minutes	-20°C → -10°C	48 Minutes	
	310	**	**	60 Minutes		50 Minutes	
	410	**	**	62 Minutes		52 Minutes	
		610	+/- 5K	8 Minutes	55 Minutes		55 Minutes
		BioMidi					
		425	+/- 5K	9 Minutes	45 Minutes	-20°C → -10°C	55 Minutes
		600W / 660W		8 Minutes	42 Minutes		55 Minutes
		BioPlus					
		500	+/- 5K	7 Minutes	45 Minutes	-20°C → -10°C	55 Minutes
	600D / 600W	7 Minutes		42 Minutes	55 Minutes		
	660D / 660W	7 Minutes		42 Minutes	55 Minutes		
	930	-		76 Minutes	63 Minutes		
	1270 / 1400	10 Minutes		45 Minutes	58 Minutes		
EF	BioMidi						
	425	+/- 9K	40 Minutes	107 Minutes	-40°C → -10°C	108 Minutes	
	BioPlus						
	600W / 660W	+/- 10K	30 Minutes	57 Minutes	-35°C → -10°C	170 Minutes	

* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14.
 ** Please contact your local distributor for current information.

Note:

RF:

Ambient temperature +25°C
 Setpoint temperature -20°C

EF (425):

Ambient temperature +25°C
 Setpoint temperature -40°C

EF (600W/660W):

Ambient temperature +25°C

Name: _____ Signature: _____ Approved (Yes / No): _____ Date: _____

Conducted by: _____

Inspected / verified by: _____

Model: _____ SN: _____

